



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection Activities: Submission to OMB for Review and Approval;  
Public Comment Request**

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Organ Procurement and Transplantation Network (OPTN)

Application Form

OMB No. 0915-0184 – Revision

Abstract: This is a request for OMB approval for revisions of the application documents used to collect information for determining if the interested party is compliant with membership and transplant program requirements contained in the Final Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN), “the OPTN final rule”.

Need and Proposed Use of the Information: Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and transplant program requirements and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, et seq. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b-8 (section 1138) requires that hospitals in which transplants are performed be members of, and abide by, the rules and requirements (as approved by the Secretary of the HHS) of the OPTN as a condition of participation in Medicare and Medicaid for the hospital. Section 1138 contains a similar provision for the organ procurement organizations (OPOs) and makes membership in the OPTN and compliance with its operating rules and requirements (that have been approved by the Secretary), including those relating to data collection, mandatory for all transplant hospitals and OPOs. These applications are developed to prompt submission of all the information required to make such membership approval decisions. In addition, hospitals wishing to obtain designation for particular (e.g., organ specific) transplant programs must submit applications to the OPTN.

Likely Respondents: Parties seeking initial OPTN membership approval and then maintenance of the existing OPTN approval. Applicants will include: every hospital seeking to perform organ transplants; every non-profit organization seeking to become an organ procurement organization; and every medical laboratory seeking to become a histocompatibility laboratory. In addition, there are other OPTN membership categories for organizations and individuals who want to participate in the organ transplant system and they too are required to fill out an appropriate application.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden - Hours

| Form Name  | Number of Respondents | Number of Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Burden Hours |
|--|-----------------------|------------------------------------|-----------------|--|--------------------|
| A New Transplant Member/Program Application- General | 8                     | 1                                  | 8               | 8                                      | 64                 |
| B Kidney (KI) Designated Program Application         | 94                    | 2                                  | 188             | 4                                      | 752                |
| B Liver (LI) Designated Program Application          | 73                    | 2                                  | 146             | 4                                      | 584                |
| B Pancreas (PA) Designated Program Application       | 56                    | 2                                  | 112             | 4                                      | 448                |
| B Heart (HR) Designated Program Application          | 43                    | 2                                  | 86              | 4                                      | 344                |
| B Lung (LU) Designated Program Application           | 50                    | 2                                  | 100             | 4                                      | 400                |
| B Islet (PI) Designated Program Application          | 4                     | 2                                  | 8               | 3                                      | 24                 |
| B Living Donor (LD) Recovery Program Application     | 46                    | 2                                  | 92              | 3                                      | 276                |
| C OPO New Program Application                        | 0                     | 1                                  | 0               | 4                                      | 0                  |
| D Histocompatibility Lab Application                 | 2                     | 2                                  | 4               | 4                                      | 16                 |
| E Change in Transplant Program Key Personnel         | 377                   | 2                                  | 754             | 4                                      | 3016               |
| F Change in Histocompatibility Lab Director          | 8                     | 1                                  | 8               | 2                                      | 16                 |
| G Change in OPO Key Personnel                        | 10                    | 1                                  | 10              | 1                                      | 10                 |
| H Medical Scientific Org Application                 | 16                    | 1                                  | 16              | 2                                      | 72                 |
| I Public Org Application                             | 6                     | 1                                  | 6               | 2                                      | 12                 |
| J Business Member Application                        | 3                     | 1                                  | 3               | 2                                      | 6                  |
| K Individual Member Application                      | 6                     | 1                                  | 6               | 1                                      | 6                  |

| Form Name        | Number of Respondents | Number of Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Burden Hours |
|------------------|-----------------------|------------------------------------|-----------------|--|--------------------|
| Total = 17 forms | 802                   | 26                                 | 1547            | 56                                     | 6046               |

Dated: February 21, 2014.

Jackie Painter

Deputy Director, Division of Policy and Information Coordination

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